IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:	
Thomas GOSTELOW	:	
Serial No.	:	Art Unit:
Filed:	:	Examiner:
For: MEDICO-SURGICAL INSTRUMENTS	:	Atty Docket: 0119/0024

SUBMISSION OF PRIORITY DOCUMENTS

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Attached hereto please find certified copies of the following UK patent applications:

United Kingdom Patent Application No. 0219773.9 filed August 24, 2002

United Kingdom Patent Application No. 0306799.8 filed March 25, 2003

Applicant requests the benefit of said August 24, 2002 and March 25, 2003 filing dates for priority purposes pursuant to the provisions of 35 USC 119.

Respectfully submitted,

Louis Woo, Reg. No. 31,730
Law Offices of Louis Woo
717 North Fayette Street
Alexandria, Virginia 22314
Phone: (703) 299-4090

Date: Aug 20, 2003

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Concept House
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NP10 8QQ

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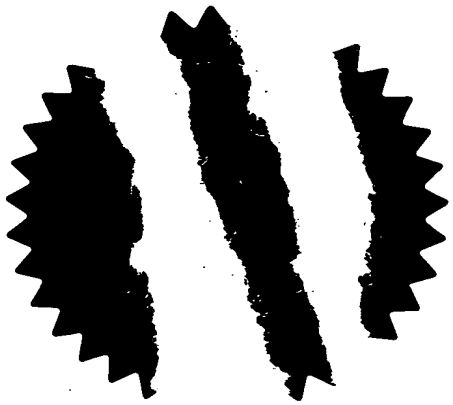

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Dated 6 August 2003

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2. Patent application number
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0219773.9

24 AUG 2002

27AUG02 E743567-1 026047
P01/7700 0.00-0219773.9

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

SMITHS GROUP PLC
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NW11 8DS

Patents ADP number *(if you know it)*

8032310001

If the applicant is a corporate body, give the country/state of its incorporation

GB

4. Title of the invention

TRACHEOSTOMY APPARATUS

5. Name of your agent *(if you have one)*

J. M. FLINT

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

765 FINCHLEY ROAD
LONDON
NW11 8DS

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1063304001

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Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

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Number of earlier application	Date of filing *(day / month / year)*

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Claim(s)	
Abstract	1
Drawing(s)	1

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Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature J J Flint Date 23/08/02

12. Name and daytime telephone number of person to contact in the United Kingdom J.A. FLINT 020 8457 8220

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TRACHEOSTOMY APPARATUS

This invention relates to tracheostomy apparatus.

Tracheostomies can be made by a conventional surgical technique or by a percutaneous technique, which is quicker and more suited to emergency situations. In the usual percutaneous technique a needle is pushed through the skin of the throat into the trachea. Entry of the needle to the trachea is detected by a loss-of-resistance technique involving a syringe filled with air connected to the needle hub. The tip of the needle is blocked while it is passing through the neck tissue so that manual pressure applied to the needle plunger encounters a resistance to movement. When the tip of the needle enters the trachea air can flow and the plunger can move forwardly, enabling entry to be detected. The syringe is then removed and a guidewire is slid along the needle. The needle is then pulled out along the guidewire, leaving the guidewire in position. The opening into the trachea is then enlarged by sliding a dilator or a series of dilators of increasing size along the guidewire into the trachea. When the opening has been enlarged sufficiently, a tracheostomy tube is slid along the guidewire, following which the guidewire can be removed. Although the apparatus involved in this technique has been used successfully for many years, the number of different components and steps is not ideal for adverse situations, such as at the site of a trauma incident, and it may not be suitable for less experienced clinicians or paramedics.

It is an object of the present invention to provide alternative tracheostomy apparatus.

According to one aspect of the present invention there is provided tracheostomy apparatus comprising a hollow needle having a cutting tip for penetrating tissue overlying the trachea, an elongate member extending along the interior of the needle such that the member can slide along its length relative to the needle, means urging the elongate member forwardly resiliently so that its patient end protrudes from the patient end of the needle when the needle penetrates the trachea and so that the member is pushed rearwardly relative to the needle during passage of the tip of the needle through tissue, indicator means towards the rear end of the needle for indicating the position of the elongate member relative to the needle, a dilator with a tapered patient end mounted on the outside of the needle and a tracheostomy tube mounted on the outside of the dilator with the tapered end of the dilator projecting from the patient end of the tracheostomy tube such that the needle can be removed from the dilator when the patient end of the dilator is located in the trachea and the dilator can be removed from the tracheostomy tube when the patient end of the tracheostomy tube is located in the trachea.

The elongate member is preferably a tube. The indicator is preferably a visual indicator.

Tracheostomy apparatus according to the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a side elevation view of the apparatus; and

Figure 2 is a cross section along the line II-II of Figure 1.

The tracheostomy apparatus comprises a needle assembly 1, a dilator assembly 2 mounted on the outside of the needle assembly and a tracheostomy tube 3 mounted on the outside of the dilator assembly. These components are supplied mounted with one another and are used with one another during the initial stage of the tracheostomy procedure.

The needle assembly 1 is similar to a Veress needle used in chest surgery and laparascopy. The assembly 1 has a straight, rigid steel needle 10 of circular section which opens axially at its patient end 11 through a cutting tip 12. An inner elongate member in the form of a hollow tube 13 extends along the needle 10 as a sliding fit. The tube 13 may be of a rigid plastics material and has a rounded, open forward or patient end 14. The rear end 15 of the tube 13 projects from the needle 10 and carries an indicator in the form of two coloured flags 16 and 17 spaced axially of one another. The forward flag 16 is red; the rear flag 17 is green. The assembly 1 also includes a helical spring 18 mounted between the needle 10 and the tube 13, urging the tube forwardly relative to the needle. The force of the spring 18 is sufficient to push the tube 13 forwardly against friction with the inside of the needle 10 and to overcome obstructions caused by tissue fragments or fluid at the tip of the needle. The force of the spring 18, however, is not sufficient to prevent the tube 13 being pushed rearwardly relative to the needle 10 when this is pushed against patient tissue. The rear end 19 of the needle assembly 1 projects at the rear of the tracheostomy assembly and the needle assembly can be withdrawn rearwardly from the tracheostomy assembly by pulling on the rear end. The passage through the inner tube 13 is continued through the hub 19, opening at the rear end of the needle assembly 1.

The dilator assembly 2 comprises a shaft 20 of a plastics material with a tapered forward end 21. The shaft 20 is a close sliding fit on the needle assembly 1 with its forward end being located about 10mm to the rear of the tip 11 of the needle 10. The natural shape of the dilator assembly 2 is curved but, while mounted on the needle assembly 1 it is maintained straight by the straight shape of the needle assembly. At its rear end, the dilator assembly has a handle 22 and a hub 23 in which the rear end 19 of the needle assembly 1 is received. The hub 23 has a transparent window 24 in one side located in alignment with the flags 16 and 17 on the inner tube 13. The position of the window 24 is such that, when the inner tube 13 is in its natural, forwards position relative to the needle 10, the rear, green flag 17 is visible through the window and the forward, red flag 16 is not visible. When the inner tube 13 is pushed rearwardly, the red flag 16 becomes visible in the window 24 in place of the green flag 17.

The tracheostomy tube 3 may be of conventional construction, comprising a flexible, helically-reinforced shaft 30 that is naturally curved but is held straight when mounted on the needle assembly 1. At its rear end 31 the tube 3 has a neck flange 32 and a standard 15mm hub or female connector 33. The tube 3 is a close sliding fit on the dilator assembly 2 with its forward, patient end 34 spaced from the forward end 21 of the dilator by about 20mm. The shaft 30 may have an inflatable sealing cuff (not shown) of the usual kind close to its patient end 34. The rear end of the dilator assembly 2 is received in the connector 33.

The tracheostomy assembly is provided as shown in the drawing with the tracheostomy tube 3 loaded on the dilator assembly 2 and with the dilator assembly loaded on the needle assembly 1. Initially, therefore, the assembly is straight, the needle assembly 1

projects from its patient end and the green flag 17 is visible. To make a tracheostomy, the cutting tip 12 of the needle assembly 1 is brought up to the skin of the throat over the trachea, usually in the cricothyroid region, with the assembly generally orthogonal to the skin surface. As pressure is applied, the inner tube 13 is pushed rearwardly by the skin surface and the red flag 16 becomes visible in the window 24. Further pressure causes the tip 12 of needle 1 to penetrate the skin and underlying tissue. The needle 10 enters the neck tissue followed by the forward, tapered end 21 of the dilator 2. When the tip 12 of the needle 1 enters the trachea, its open end 11 is no longer occluded by tissue so the spring 18 can move the inner tube 13 to its forward position, causing the green flag 17 to be visible. This provides an indication to the clinician that the trachea has been entered. When the needle 10 enters the trachea a gas passage is provided into the trachea via the passage through the inner tube 13. If the tracheostomy assembly should be inserted too far, so that it contacts the posterior wall of the trachea, this will push back the inner tube 13 and cause the red flag 16 to appear as a warning to the clinician. This warning flag 16 will also appear if the tip 12 of the assembly should contact an obstruction within the trachea.

The clinician then angles the assembly so that the tip 12 points down the trachea, that is, towards the patient's feet. He then continues to push in the assembly until the tip 34 of the tracheostomy tube 3 is adjacent the skin surface, at which point the tip 21 of the dilator 2 should be located in the trachea. He then pulls out the needle assembly 1 by gripping its rear end 19 while holding the handle 22 so that the dilator 2 is not pulled out. After the needle assembly 1 has been removed he continues to push in the assembly of the dilator 2 and the tracheostomy tube 3. The taper 21 on the dilator 2 enlarges the opening through the neck tissue sufficiently for the tracheostomy tube 3 to be pushed in. As the dilator 2 emerges into

the trachea it bends to its natural shape pointing down the trachea. This helps guide the tracheostomy tube 3, which also bends as it is inserted. Once the tracheostomy tube 3 has been fully inserted, with its flange 31 abutting the skin surface, the dilator 2 is removed and the cuff on the tracheostomy tube is inflated to seal with the trachea.

The apparatus of the present invention provides a clear indication of entry into the trachea without the need to use a loss-of-resistance syringe. It also provides an indication of contact with the posterior wall. The apparatus can be provided ready assembled for immediate use making it ideally suited for emergency applications. The apparatus is easy to use making it safe for use by less skilled people.

The apparatus could be modified in various ways. For example, the elongate member extending along the bore of the needle need not be a tube but could be a rod or the like. Instead of a visual indicator, the indicator could provide an audible indication such as by completing an electrical circuit on sliding forwards or rearwards.

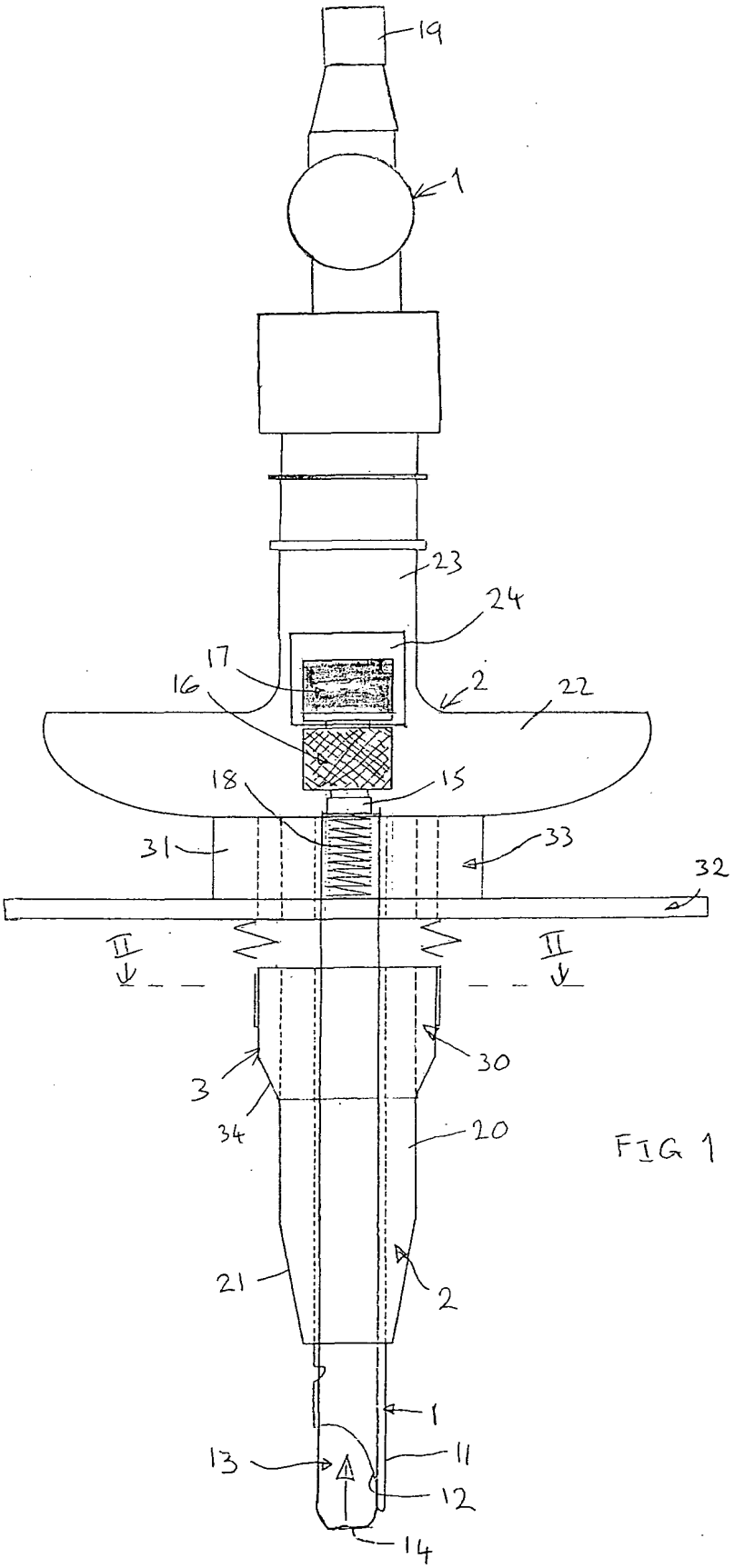
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FIG 1

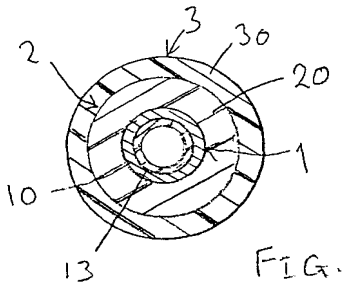
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FIG. 2

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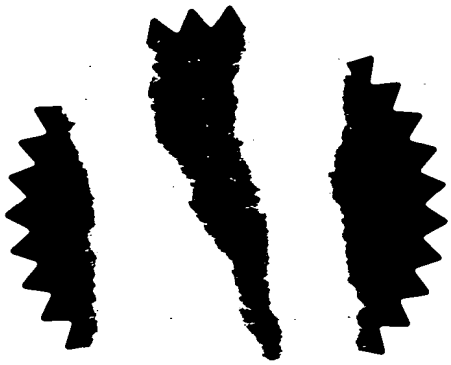

Signed P. Mahoney

Dated 29 July 2003

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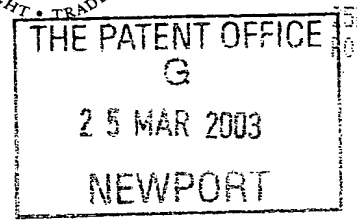

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01/7700 0.00-0306799.8

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1. Your reference — 0300070

2. Patent application number *(The Patent Office will fill in this part)* — 0306799.8 — 25 MAR 2003

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

SMITHS GROUP PLC
765 FINCHLEY ROAD
LONDON
NW11 8DS

Patents ADP number *(if you know it)* — 8032310001

If the applicant is a corporate body, give the country/state of its incorporation — GB

4. Title of the invention

VENTILATION INSTRUMENTS

5. Name of your agent *(if you have one)* — J. M. FLINT

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

765 FINCHLEY ROAD
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Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

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8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

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b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
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Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
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Any other documents *(please specify)*	

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Signature J. Flint Date 24 MARCH 2003

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VENTILATION INSTRUMENTS

This invention relates to ventilation instruments.

Various procedures and instruments are used to ventilate patients with an upper airway obstruction, involving forming a passage into the trachea through neck tissue. One technique used in emergency situations is percutaneous transtracheal ventilation. In this technique a sharp-tipped needle penetrates the trachea and the external, machine end of the needle is connected to a jet ventilation machine so that breathing gas is supplied to the trachea via the needle, which is left in position. This arrangement can be used to provide emergency ventilation for up to about one hour, which is usually sufficient time for the patient to be provided with alternative ventilation. The advantage of this procedure is that it can be carried out relatively easily by ambulance crew and paramedics and it does not involve the need for cutting with a scalpel. The procedure does, however, have several disadvantages. First, there is a risk that the needle will not be inserted to the correct depth, because of variations in thickness of neck tissue overlying the trachea. If the needle is not inserted far enough its tip may be located in the anterior tissues surrounding the trachea instead of in the trachea itself. If inserted too far, the needle may damage the posterior wall of the trachea. Second, because the ventilation gas emerges through the open tip of the needle and the bore of the needle is relatively small compared with a tracheal tube, the gas emerges as a jet directed longitudinally of the needle and towards the posterior wall of the trachea. Where the gas jet impinges on the tissue of the trachea it may cause drying and necrosis.

Another problem with emergency ventilation instruments is that it is usually necessary to hyperextend the neck in order to provide access to the trachea. Where the patient has suffered neck injury, or is suspected of having suffered a neck injury it is important that there is minimal movement of the neck. This is a particular disadvantage because patients requiring emergency ventilation are often those that have been involved in an accident of the kind that can cause neck injury.

It is an object of the present invention to provide an alternative ventilation instrument.

According to one aspect of the present invention there is provided a medico-surgical ventilation instrument comprising an outer needle having a sharp tip adapted to penetrate the trachea through neck tissue, an inner tubular member located within the needle, the inner tubular member having a bore extending longitudinally of the member and opening towards the forward, patient end of the member through an opening, the tubular member having means towards its rear, machine end by which breathing gas can be supplied to the bore, means for urging the inner tubular member forwardly relative to the needle, such that the forward end of the inner member is located forwardly of the needle tip before use but is displaced rearwardly during passage through the neck tissue by engagement with the tissue and moves forwardly relative to the needle when the trachea is penetrated, and the instrument being arranged such that movement of the inner member relative to the needle can be perceived by the user so that the user knows that the trachea has been penetrated and that gas can be supplied to the inner member.

The inner tubular member is preferably closed at its patient end and has a side aperture close to the patient end through which gas can flow. Preferably, the inner member has two side apertures diametrically opposite one another. The inner member may be urged forwardly by a spring. The instrument preferably includes a visual indicator towards its rear end by which movement of the inner member can be perceived.

A ventilation instrument according to the present invention will now be described, by way of example, with reference to the accompanying drawing, in which:

Figure 1 is a side elevation view of the instrument; and

Figure 2 is a cross section along the line II-II of Figure 1;

The instrument is similar to a Veress needle used in chest surgery and laparoscopy. The instrument 1 has a straight, rigid steel needle 10 of circular section which opens axially at its patient end 11 through a sharp, bevelled cutting tip 12. An inner, elongate member in the form of a hollow tube 13 extends along the needle 10 as a sliding fit. The tube 13 may be of a metal or a rigid plastics material and has a rounded, closed forward or patient end or tip 14. Two longitudinally-elongated side openings 15 are located diametrically opposite one another close to the tip 14, which open into the bore of the tube 13. The rear end 16 of the tube 13 projects from the needle 10, is open and communicates with a bore 17 extending rearwardly along a handle 18.

The rear end 16 of the inner tube 13 also carries a visual indicator in the form of two coloured flags 26 and 27 spaced axially of one another. The forward flag 26 is red; the rear flag 27 is green. A helical spring 28 towards the rear of the needle 10 between the needle and the tube 13, urges the tube forwardly relative to the needle. In the natural, forward position of the inner tube 13, before use, the two side openings 15 are exposed forwardly of the patient end 11 of the needle 10. The force of the spring 28 is sufficient to push the tube 13 forwardly against friction with the inside of the needle 10 and to overcome obstructions caused by tissue fragments or fluid at the tip of the needle. The force of the spring 28, however, is not sufficient to prevent the tube 13 being pushed rearwardly relative to the needle 10 when this is pushed against patient tissue. The handle 18 terminates at its rear, machine end in a male connection 19 through which opens the bore 17. Jet ventilation equipment 20 is connected to the connection 19, and hence to the inner tube 13 by tubing 21.

The handle 18 has a transparent window 30 in one side located in alignment with the flags 26 and 27 on the inner tube 13. The position of the window 30 is such that, when the inner tube 13 is in its natural, forward position relative to the needle 10, the rear, green flag 27 is visible through the window and the forward, red flag 26 is not visible. When the inner tube 13 is pushed rearwardly, the red flag 26 becomes visible in the window 30 in place of the green flag 27.

Initially, in the natural state of the instrument, the inner tube 13 projects from the forward, patient end 11 of the needle 10 and the green flag 27 is visible. To provide ventilation to a patient, the cutting tip 12 of the needle 10 is brought up to the skin of the throat over the trachea, usually in the cricothyroid region, with the assembly generally

orthogonal to the skin surface. As pressure is applied, the inner tube 13 is pushed rearwardly by the skin surface and the red flag 26 becomes visible in the window 30. Further pressure causes the tip 12 of the needle 10 to penetrate the skin and underlying tissue. When the tip 12 of the needle 1 enters the trachea, its open end 11 is no longer occluded by tissue so the spring 28 can move the inner tube 13 to its forward position, causing the green flag 27 to become visible. This provides an indication to the clinician that the trachea has been entered. When the needle 10 enters the trachea a gas passage is provided into the trachea via the bore of the inner tube 13. If the instrument should be inserted too far, so that it contacts the posterior wall of the trachea, this would push back the inner tube 13 and cause the red flag 26 to appear as a warning to the clinician. This warning flag 26 will also appear if the tip 12 of the instrument should contact an obstruction within the trachea.

When the tip 12 of the needle 10 is correctly located in the trachea, the openings 15 in the inner tube 13 are exposed and breathing gas can be supplied to the instrument from the ventilation equipment 20 emerging into the trachea via the openings 15 in the inner tube.

The instrument of the present invention provides a clear indication of entry into the trachea and thereby makes it apparent to the user when gas can be supplied safely. It also provides an indication of contact with the posterior wall. The instrument is easy to use making it safe for use by less skilled people. Because the gas emerges from side openings there is less risk of tracheal tissue being damaged by exposure to a gas jet. Another advantage of the instrument is that it enables ventilation without having to hyperextend the neck so that it lends itself particularly for use with patients having a neck injury or a suspected neck injury.

The instrument could be modified in various ways. Instead of a visual indicator, the indicator could provide an audible indication such as by completing an electrical circuit on sliding forwards or rearwards, or it could have some form of tactile indicator. The instrument could have a lock to fix the inner tube in the extended position after penetration of the trachea so as to prevent contact with the sharp cutting tip of the needle while in the trachea. This could be advantageous where the patient is being transported since there may be a risk of the instrument being moved by vibration or jolting of a vehicle or trolley. Locking the inner tube in the extended position could also help reduce the risk of injury by inadvertent contact with the needle tip after use. The instrument could have an adjustable flange, such as of the kind described in GB 2227941, to enable it to be secured to the neck after insertion.

It is not essential that the inner tube open through side apertures since it could open through its end, although this would give rise to jetting problems. These problems might be reduced by having side apertures in addition to an open end so that some of the gas pressure is dissipated by lateral flow from the side apertures. Where side apertures are used, the instrument could be arranged so that the side apertures are totally blocked by the needle when the inner tubular member is in its retracted position. In this way, gas could be supplied to the instrument continuously but would be prevented from emerging at the patient end of the instrument during passage through neck tissue, and would automatically emerge into the trachea when the trachea is penetrated.

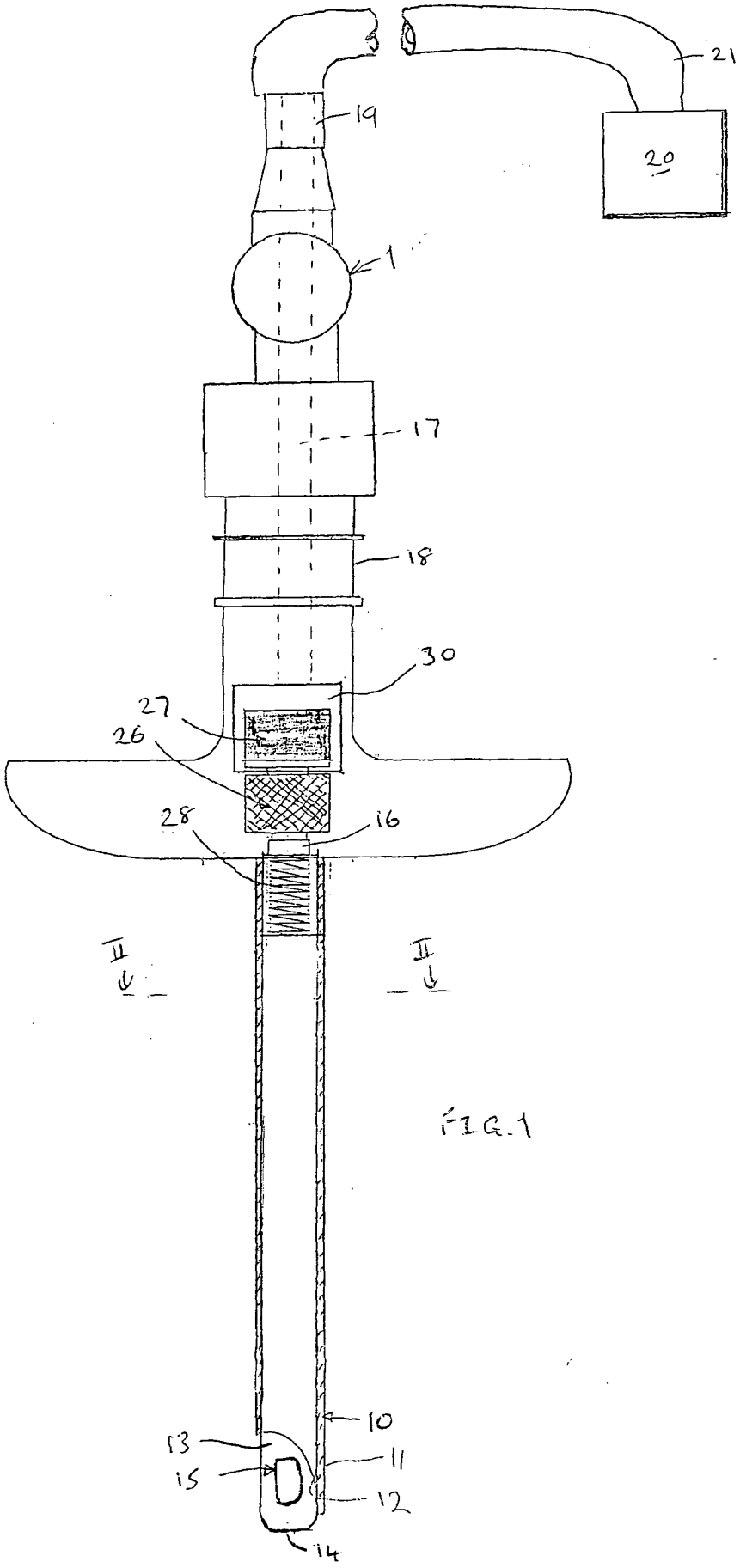

FIG. 1

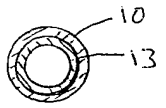

FIG. 2